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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/834,769 | 04/13/2001 | John L. Robertson | 2693 | 3757 |
| 26822 | 7590 | 04/08/2004 | EXAMINER | |
| WALTER A. HACKLER 2372 S.E. BRISTOL, SUITE B NEWPORT BEACH, CA 92660-0755 | | | ALEXANDER, LYLE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1743 | |

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/834,769

Applicant(s)

ROBERTSON ET AL.

Examiner

Lyle A Alexander

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 21-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1743

In response to the 12/15/032 Appeal Brief, the search was updated and a new reference pertinent to the merits of this case was found. The prosecution has been reopened in light of this new reference and the below rejection will replace the 8/13/03 final rejection.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 22-25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Douglas et al.

Douglas et al. teach a diagnostic testing device (1) comprising a capillary tube (2), a support member (3), a handle portion (15), vent holes (8 and 9), slot (16), spreading/filtering layer (4) which is in communication with reagent layer (5) and carrier layer (6). The claimed casing has been read on the taught mating of support member (3) and carrier layer (6). The claimed pocket has been read on the taught capillary tube (2). The claimed sample metering means comprising a sample pad and a feed element has been read on the spreading/filtering layer (4). The sample pad has been read on layer (4) and the feed element read on the interface of the bottom of the tube (2) contacting layer (4). The claimed testing assembly has been read on the taught reagent layer (5).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1743

Claims 1 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lu et al. (USP 6,203,757) in view of Douglas et al. (USP 5,948,695).

Lu et al. teach a diagnostic testing (20) comprising a port hole (24) to receive a sample that is in fluid communication with a sample receiving/distribution web (25) that distributes the sample to the test strips (26). There is base member (23) that supports the web (25) and strips (26) that is covered by face plate (22). The claimed casing has been read on the taught base member (23) mated with face plate (22). The claimed pocket has been read on the taught port hole (24). The claimed sample metering means has been read on the taught receiving/distribution web (25). The claimed testing assembly has been read on the taught test strips (26).

Lu et al. is silent to the claimed " pocket extending outwardly from the casing ".

Douglas et al. teach a diagnostic testing device (1) having a capillary tube (2) extending outwardly from the surface the device (1). Column 6 lines 5+ teach the capillary tube (2) is advantageous because the body fluid sample can be collected by touching the tube (2) to the place of fluid collection. This enables the user to collect the blood sample at any location on the body and eliminates the need for the user to form a drop of the fluid that must be precisely place on the test device. The capillary tube (2) precisely collects the appropriate volume that eliminates the user to be concerned with collecting the necessary volume of fluid. The need for additional pieces of collection equipment, such as eye droppers or pipettes, that require additional manipulation and the possibility of contamination of the sample or user are also eliminated by the capillary tube (2).

Art Unit: 1743

It would have been within the skill of the art to modify Lu et al. in view of Douglas et al. and use a capillary tube (2) on top of the port hole (24) to aid in the collection of the sample to gain the above advantages.

The modified device of Lu et al. is also silent to the claimed plurality of feed inlets. It is known that sample will travel faster through a single inlet to a single test strip than through a complex network with a single opening that distributes to multiple test strips. Additionally, less sample would be required to directly contact the test strip than through a network. It would have been within the skill of the art to further modify Lu et al. and provide a plurality of openings to each of the plurality of test strips to gain the above advantages.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lu et al. (USP 6,203,757) in view of Douglas et al. (USP 5,948,695) further in view of Cipkowski.

See Lu et al. and Douglas et al. *supra*.

The modified device of Lu et al. is silent to the claimed plurality of feed inlets.

Cipkowski teaches a test device comprising a test card(25) that encases a plurality of test strips(26-30). Apertures(51) communicate to each of the corresponding test strips(26-30). It is advantageous to give the sample direct access to each test strip to speed the results of the test and require less sample (e.g. sample will travel faster through a single inlet to a single test strip than through a complex network and will require less fluid because the network will not have to be saturated). It would have been within the skill of the art to further modify Lu et al. further in view of Cipkowski and

Art Unit: 1743

prove a plurality of individual aperture to each of the plurality of test strips to gain the above advantages.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al. in view of Cipkowski.

See Douglas et al. and Cipkowski supra.

Douglas et al. is silent to the claimed plurality of different test strips that require a plurality of respective feed inlets.

Cipkowski teaches a test card(25) comprising a plurality of test strips for a plurality of commonly screened for analytes. It is advantageous to simultaneously screen for multiple analytes from a single sample to facilitate quicker results, require less technician time and avoids having to store the sample. It would have been within the skill of the art to modify Douglas et al. and proved multiple test strips with their corresponding apertures to gain the above advantages.

Response to Arguments

Applicant's arguments with respect to claims 1 and 21-25 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Art Unit: 1743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lyle A Alexander
Primary Examiner
Art Unit 1743



approved .


Jill Warden
Supervisory Patent Examiner
Technology Center 1700